

REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance or in better condition for appeal.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-7, 9-24 and 32-41 were pending in this application. Claims 42-56 have been added. Support for the new claims is found throughout the specification as originally filed. For example, support for the new claims is found on pages 50, 77, 89, 133, 139, 140 and Figure 12 of the specification. No new matter has been added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE DOUBLE PATENTING REJECTIONS ARE OVERCOME

Claims 1-7, 9-24 and 32-41 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-3, 5-20 and 29-37 of U.S. Patent No. 6,582,662 to Kellogg et al. in view of U.S. Patent 6,063,589 to Kellogg et al. In addition, claims 1-7, 9-23 are provisionally rejected under the judicially created doctrine of obviousness type double patenting as allegedly being unpatentable over claims 1-22 of copending Application No. 10/746,821 in view of U.S. Patent No. 6,063,589 to Kellogg et al. Finally, claims 37 and 38 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-2 of U.S. Patent 6,709,869 to Mian et al. in view of U.S. Patent 6,063,589 to Kellogg et al. Applicants respectfully traverse these arguments with the following arguments.

a.) The double patenting rejection over U.S. Patent No. 6,582,662 (“the ‘662 patent”) in view of U.S. Patent No. 6,063,589 (“the ‘589 patent”) is overcome: This rejection is not valid being that double patenting rejection is misused in the Office Action. In the Office Action, the obviousness-type double patenting is applied as if it were a section 103 rejection. The ‘662 patent should not be combined with another document. Moreover, the Office Action does not indicate which part of the ‘662 patent is relevant.

The Office Action correctly points out that the present application differs from the cited claims in the ‘662 patent in several ways. The cited claims do not teach or suggest a reagent aliquotting manifold, bulk reagent chamber or overflow reservoir. The claimed bulk reagent reservoir and aliquotting manifold, as described in the specification of the present application, offer distinct advantages over current high throughput screening where both samples and reagents must be aliquotted individually. There is no teaching or suggestion a method of expediting high throughput screening in the claims of the ‘662 patent.

Even if the claims of the ‘662 are combined with the ‘589 patent, the combined references would not render the claimed invention obvious without proper hindsight. The Examiner is reminded that only with proper hindsight would one be able to contemplate these essential elements that allow for high throughput screening. It is impermissible to engage in a hindsight reconstruction of the claimed invention, using the Applicant’s structure as a template, and selecting elements from references to fill in the gaps. *Interconnect Planning*, 744 F.2d 1132, 1143 (Fed. Cir. 1985). Only through the exercise of impermissible hindsight has the cited reference been selected and relied upon by the Office.

The alleged reagent aliquotting manifold in the ‘589 patent is used for entirely different purposes than the aliquotting manifold in the present invention. Note that claim 1 of the present invention claims “one of a plurality of aliquotted reagent reservoirs...wherein each of said sample reservoir and aliquotted reagent reservoir is fluidly connected to at least one of a plurality of detection reservoirs through a microchannel.” These elements do not appear in the claims of the ‘589 patent.

Reconsideration and withdrawal of the double patenting rejections are earnestly requested.

b.) The double patenting rejection over Application No. 10/746,821 (“the ‘821 application”) in view of U.S. Patent No. 6,063,589 (“the ‘589 patent”) is overcome: For

reasons discussed above, the double patenting rejection is misapplied in the Office Action. Even if the statute were not misapplied, there are no grounds for raising such an objection. The '821 application involves dilution of a sample as it moves from one chamber to another chamber containing diluent. Centripetal force motivates the flow of fluid between the respective chambers. The '821 application does not teach or suggest an aliquotting manifold and the detection reservoirs connected to microchannels. In other words, the important elements of the claim are missing in the cited claims of '821 patent.

Reconsideration and withdrawal of the double patenting rejections are earnestly requested.

c.) The double patenting rejection over U.S. Patent No. 6,709,869 (“the ‘869 patent”) in view of U.S. Patent No. 6,063,589 (“the ‘589 patent”) is overcome: For reasons discussed above, the double patenting rejection is misapplied in the Office Action. In the cited claims of the '869 patent, the claim specifies “a multiplicity of reagent chambers.” The Office Action identifies the discrepancy with the present application, noting that a reagent manifold is lacking. As previously stated, the '589 patent does not teach, suggest or provide any motivation for using the 'reagent manifold' as claimed in claims 37-38 of the present application.

Reconsideration and withdrawal of the double patenting rejections are earnestly requested.

III. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

Claims 1-7, 11, 14-16, 32-39 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by European publication 0 608 006 to Abaxis, Inc. (hereinafter “Abaxis”). The Office Action alleges that Abaxis discloses analytical rotors which are microsystem platforms that use centripetal force to move microvolumes of fluids throughout the device. The Office Action also alleges that a bulk diluent reservoir described in Abaxis is equivalent to Applicants' claimed bulk diluent reservoir, while the diluent metering chamber is equivalent to Applicants' claimed reagent manifold. The Office Action further contends that the mixing chamber described in Abaxis is equivalent to the microfluidic mixing channels disclosed in the present invention. These rejections are respectfully traversed. The cited references do not anticipate the instant invention.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applying the law to the instant facts, the reference relied upon by the Office Action does not disclose, suggest or enable Applicants' invention.

The Office Action argues that microfluidic mixing vessels disclosed in the present application are essentially the same as the mixing chambers suggested in Abaxis. Furthermore, the Office Action states that "as there is no showing of unexpected results in using a microchannel mixer, as opposed to the mixing chamber taught by Abaxis, the rejection is maintained." As discussed below, the invention claimed in the present application substantially differs from Abaxis.

Many of the elements present in the pending claims of the present application are not taught or suggested by Abaxis. The pending claims of the present application claims a "microfluids structure wherein each of said sample reservoir and aliquotted reagent reservoir is fluidly connected to at least one of the plurality of detection reservoirs through a microchannel." In Abaxis, only the separation chamber is fluidly connected to the reservoir. The pending claims further specify "a reagent manifold comprising a microchannel positioned radially across the surface of the platform wherein the aliquotting reagent reservoir is fluidly connected to the overflow reservoir." Abaxis does not teach or suggest such a manifold. The disc in claim 1 further comprises "a mixing microchannel, wherein each mixing microchannel is fluidly connected to a sample reservoir and one or a plurality of aliquotted reagent reservoirs by a microchannel." Abaxis never suggests the possibility of using mixing microchannels.

In the present application, rotation of the disk forces the fluid from these chambers into the microfluidics layer where they are intimately mixed. Such an intricate setup allows for the analysis or screening of a multitude of samples. The applicants achieve the proper coordination between the reservoir and microfluids layer through microchannels that protrude from the

reservoir layer to the microfluidics layer (see Figures 5b and 6 of the application as originally filed). The mixing microchannels are configured to achieve the proper degree of mixing for the appropriate amount of times (pages 25-26 of the application as originally filed). None of these features are taught or suggested in Abaxis. Abaxis does not disclose a microfluids layer, a means of performing multiple simultaneous reactions on the disc or a means of connecting the components in such a fashion as to achieve the desired high throughput screening.

Thus, all of the important elements in the pending claims which enable one skilled in the art to perform the miniaturized high throughput screening techniques are not taught or suggested in Abaxis. The patent specification of Abaxis makes it clear that the invention was purely for separation purposes, not high throughput screening and biological/chemical reactions (see for instance column 9, lines 51-58 of Abaxis). Consequently, one of skill in the art would not look to Abaxis for creating a means of generating a miniaturized high throughput screening devices and methods claimed in the present application. Importantly, Abaxis provides no teaching or motivation of how the technology could be applied to high throughput screening miniaturization devices of the present application.

Consequently, reconsideration and withdrawal of the Section 102 rejections are earnestly requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 1-7, 9-24, and 32-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,582,662 ("Kellogg '662") in view of U.S. Patent No. 6,063,589 ("Kellogg '589"). Applicants respectfully traverse this rejection with the following argument.

Kellogg '662 and Kellogg '589 patents are and have been co-owned at all times during their pendency and to date. Moreover, the two references were commonly owned at the time the invention was made. The Kellogg '662 and Kellogg '589 patents were originally owned by Gamera Biosciences Corporation, from which the current real party in interest, Tecan Trading AG, acquired all right, title and interest. As a consequence, therefore, the Kellogg '662 and Kellogg '589 patents are commonly owned with the instant application, and are thus unavailable as prior art to support the asserted rejection on §103 grounds. MPEP § 706.02(1)(1). Thus, the Action fails to set out a *prima facie* case of obviousness.

Consequently, withdrawal of the Section 103 rejections is earnestly requested.

BEST AVAILABLE COPY

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested; and, the Office Action is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: Deborah L. Lu
Thomas J. Kowalski
Reg. No. 32,147
Deborah L. Lu
Reg. No. 50,940
Telephone: (212) 588-0800
Facsimile: (212) 588-0500